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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,456	02/13/2004	Peter Strong	672601-2001	9496
20/999 7590 04/22/2008 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151				
EXAMINER				
KIM, YUNSOO				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
04/22/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/779,456

**Applicant(s)**

STRONG, PETER

**Examiner**

YUNSOO KIM

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-33 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6, 7, 10-27, 37-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 8, 9, 28-33, 35 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1        Claims 1, 3-33 and 35-43 are pending.

Claims 1, 3, 5, 8, 9, 28-33 and 35-36 read on elected species of aeroallergen are being examined.

2.        The declaration of Peter Strong under 37 CFR 1.132 filed on 2/5/08 has been acknowledged.

3.        The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4.        Claims 1, 3, 5, 8, 9, 28-33 and 35-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata et al. (IDS reference AQ, of record) in view of Clinical Report (Pediatrics, 1997, vol. 100(1):143-152, of record) as evidenced by the specification of the instant application on p. 13 (newly cited), p.19 (of record), Sigma Chitin powder product sheet (of record), WO 97/20576, of record (IDS reference), Kim et al. (J. Dentistry for Children, 2004, vol. 71:126-130), of record, and U.S. Pat. No. 6,080,762, of record, for the reasons set forth in the office action mailed 10/5/07.

Applicant's arguments filed on 2/5/08 and the Declaration of Peter Strong have been fully considered but they were not persuasive.

Applicant traversed the rejection based on that the claim as currently amended, one of the ordinary skill in the art would not recognize the method used in the Shibata reference as in the method of treating allergy. Applicant further traversed that the induction of allergy in Shibata reference instills the lungs via i.t. while the claimed involves the respiratory tract or nasal passage. Moreover, the Shibata reference does not teach or suggest a method of treating allergies as the Shibata reference only teaches the method of reducing serum IgE levels and lung eosinophilia.

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The claimed invention is a method of treating an allergy by administering of chitin microparticle intranasally. The method encompasses a treatment of "allergies to aeroallergens". Applicant asserts that the induction of allergy as in the Shibata reference and the claimed invention are not identical and the combination of references is not obvious. However, the induction of allergy via different routes (e.g. i.t. vs. i.n.) which presumes to require different mechanisms of treatments, is not claimed. The claimed method encompasses administering of chitin microparticles and induction of allergy with various routes is irrelevant.

Contrary to Applicant's assertion that the Shibata reference does not teach or suggest a method of treating allergies, the specification of instant application on p. 17-18 overlapping paragraph, the parameters measured in the allergy models are serum IgE and the reduction of serum IgE is an indication of allergy treatment. Furthermore, Applicants extrapolates the results of Examples 4-7 in reduction of IgE as an indication of treatment of allergy with chitin microparticles. Given that the reduction of serum IgE is closely related in the treatment of allergy, the results shown in the Shibata reference suggests the allergy treatment with chitin microparticles.

As discussed above, the scope of the claimed invention includes a method for treating an allergy to aeroallergens via intranasal delivery of chitin microparticles, the benefit of intranasal delivery and the intranasal delivery of chitin microparticles and a particular dose range were suggested in Clinical Reports, WO 97/20576, Kim and the '762 patent, respectively. Therefore the combination of reference remains obvious.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim  
Patent Examiner  
Technology Center 1600  
April 17, 2008

/ILIA OUSPENSKI, Ph.D./  
Primary Examiner, Art Unit 1644

**Application Number****Application/Control No.**

10/779,456

**Examiner**

YUNSOO KIM

**Applicant(s)/Patent under  
Reexamination**

STRONG, PETER

**Art Unit**

1644